

**U.S.S.N. 10/081,569
Gholam-Reza Zadno-Azizi, et al
PRELIMINARY AMENDMENT**

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B4*
recoverable material so as to accomplish an initial insertion state and an expanded anchoring state. A valve support transitions between the resilient seal portion and the valve body to insure that the states do not change the threshold opening pressure. Insertion devices may be employed to position and actuate a change of state of the frame in the body duct or passageway.

REMARKS

Any fees that may be due in connection with this application throughout its pendency may be charged to Deposit Account No. 50-1213.

The specification is amended to correct obvious typographical and grammatical errors. In particular, the amendment to the paragraph on page 1, lines 2-6, replaces the typographically incorrect date "6" for --16-- for clarity. The amendment to the paragraph on page 2, lines 2-6, of the specification replaces the inadvertently placed word "artificial" with --native-- for clarity. No new matter has been added to the specification section.

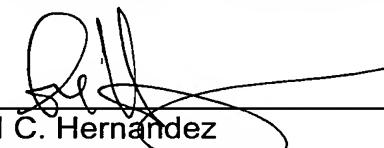
The abstract is amended to correct obvious typographical and grammatical errors. No new matter has been added to the abstract section.

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In view of the amendments and above remarks, entry of the amendments and examination of the application on the merits are respectfully requested.

Respectfully submitted,
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Gholam-Reza Zadno-Azizi, et
al.

Serial No.: 10/081,569

Filed: February 21, 2002

For: **BODY FLUID FLOW
CONTROL DEVICE**

Art Unit: 3738

Examiner: Unassigned

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**ATTACHMENT TO PRELIMINARY AMENDMENT
(MARKED-UP PARAGRAPHS)**

IN THE SPECIFICATION

Please amend the paragraph on page 1, lines 2-6, as follows:

This is a continuing application of U.S. Patent Application No. 09/397,218, filed September [6] 16, 1999, which is a continuing application of U.S. Patent Application No. 08/931,552, filed September 6, 1997, and issued as U.S. Patent No. 5,954,766, which disclosures of the above are incorporated herein by reference.

Please amend the paragraph on page 2, lines 2-6, as follows:

Native valves are also found in cardiovascular systems. In veins, native venous valves promote one-way flow toward the heart from the periphery. Diseases exist such as venous thrombosis and thrombophlebitis which can render native venous valves incompetent, resulting in edema. Replacement of these [artificial] native valves with artificial ones could provide substantial health benefits.

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Please amend the paragraph beginning on page 9, line 21, through page 10, line 1, as follows:

The frame is to be capable of two states, an insertion state and an anchoring state. The anchoring state is larger than the insertion state by the laterally extending resilient elements being [outwardly] outward of the insertion position of these elements when they are in the anchor state.

Please amend the paragraph on page 11, lines 12-23, as follows:

Another mechanism for providing an elongate expander and insertion tool is illustrated in Figure 12. The device includes an outer sheath 88 into which is positioned a fluid flow control device which has longitudinally extending elements that are of spring material. The elements are bent such that the frame is radially constricted. The size of the [sheath] sheath's inner diameter is such that the spring elements are not bent to the point that they exceed the elastic limit. A ram 90 extends into the sheath 88 to force the fluid flow control device from the end of the sheath. As the device is released from the sheath 88, it will naturally expand to the anchored state. This same mechanism may be employed with any of the devices for placement regardless of whether the mechanism for expansion is deformation, heat recovery or resilience. Naturally, the ram 90 can accommodate a heating element or balloon mechanism depending upon the appropriate need.

Please amend the paragraph on page 12, lines 8-16, as follows:

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Considering the use of these devices, the thresholds are selected with the appropriate pressures in mind. With incontinence, the threshold pressure is high enough to prevent leakage as normal pressure builds in the bladder. When the bladder is to be voided, abdominal pressure is used. The threshold pressure is also low enough that the abdominal pressure will overcome the resistance and allow flow. Where placement is in the cardiovascular system, minimum resistance to flow in one direction may be designed into the valve. In this application, however, substantial resistance to flow is designed into the valve to eliminate flow in one direction for all pressures contemplated.

IN THE ABSTRACT

Please amend the paragraph on page 16, lines 2-13, as follows:

A device to provide body fluid flow control in the form of a valve to be located within a duct or passageway. The device is controlled through pressure above a preselected threshold. Bulk resilience about a passageway in a valve body provides the mechanism for controlled flow. One-way valve operation may be provided through a flap or through a pressure differential on the valve body depending upon the direction of flow. A frame structure positioned within a resilient seal includes longitudinally [elongate] elongated elements which may be of spring material, malleable material or heat recoverable material so as to accomplish an initial insertion state and an expanded anchoring state. A valve support transitions between the resilient seal portion and the valve body to insure that the states do not change the threshold opening pressure.

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Insertion devices may be employed to position and actuate a change of state of the frame in the body duct or passageway.

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